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STENT DELIVERY FOR BIFURCATED VESSELS

Inventors: BERNARD ANDREAS, a citizen of The United States, residing at
633 California Way
Redwood City, CA 94062

JEFFRY J. GRAINGER, a citizen of The United States, residing at
95 Palmer Lane
Portola Valley, CA 94028

Assignee: XTENT, INC.
125 Constitution Dr.
Menlo Park, CA, 94025

A Delaware corporation

Entity: Small business concern

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 650-326-2400

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CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. Patent Application Serial No. 10/637713 (Attorney Docket No. 021629-000340US), filed August 8, 2003, which is a continuation-in-part of co-pending application Serial No. 10/412,714, (Attorney Docket No. 21629-000330), filed April 10, 2003, which is a continuation-in-part of application Serial No. 10/306,813, (Attorney Docket No. 21629-000320), filed November 27, 2002, which is a non-provisional application of U.S. Provisional Application Serial Nos.: 60/336,767, (Attorney Docket No. 21629-000300), filed December 3, 2001, and 60/364,389, (Attorney Docket No. 21629-000310), filed March 13, 2002, the disclosures of which are all fully incorporated herein by reference. This application is also a continuation-in-part of U.S. Patent Application Serial No. 10/738666 (Attorney Docket No. 021629-000510US), filed December 16, 2003, which is a non-provisional application of U.S. Provisional Patent Application No. 60/440,839 (Attorney Docket No. 21629-000500US), filed January 17, 2003, the disclosures of which are all fully incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates generally to stents and stent delivery catheters for deployment in the coronary arteries and other vessels. More specifically, the invention relates to stents and stent delivery systems for treating bifurcated vessels.

BACKGROUND OF THE INVENTION

[0003] Stenting has become an increasingly important treatment option for patients with coronary artery disease. Stenting involves the placement of a tubular prosthesis within a diseased coronary artery to expand the arterial lumen and maintain the patency of the artery. Early stent technology suffered from problems with restenosis, the tendency of the coronary artery to become re-occluded following stent placement. However, in recent years, improvements in stent design and the advent of drug-eluting stents have reduced restenosis rates dramatically. As a result, the number of stenting procedures being performed in the United States, Europe, and elsewhere has soared.

[0004] Stents are delivered to the coronary arteries using long, flexible vascular catheters typically inserted through a femoral artery. For self-expanding stents, the stent is simply released from the delivery catheter and it resiliently expands into engagement with the vessel wall. For balloon expandable stents, a balloon on the delivery catheter is expanded which expands and deforms the stent to the desired diameter, whereupon the balloon is deflated and removed.

[0005] Current stent delivery technology suffers from a number of drawbacks. For example, current stent delivery catheters are not capable of customizing the length of the stent *in situ* to match the size of the lesion to be treated. While lesion size may be measured prior to stenting using angiography or fluoroscopy, such measurements may be inexact. If a stent is introduced that is found to be of inappropriate size, the delivery catheter and stent must be removed from the patient and replaced with a different device of correct size.

[0006] Moreover, current stent delivery devices cannot treat multiple lesions with a single catheter. Current devices are capable of delivering only a single stent with a single catheter, and if multiple lesions are to be treated, a new catheter and stent must be introduced for each lesion to be treated.

[0007] Further, current stent delivery devices are not well-adapted for treating vascular lesions that are very long and/or in curved regions of a vessel. Current stents have a discrete length that is relatively short due to their stiffness. If current stents were made longer so as to treat longer lesions, they would not conform well to the curvature of vessels or to the movement of vessels on the surface of the beating heart. On the other hand, any attempt to

place multiple stents end-to-end in longer lesions is hampered by the inability to maintain appropriate inter-stent spacing and to prevent overlap of adjacent stents.

[0008] Many of the above shortcomings are addressed by various currently pending patent applications assigned to the assignee of the present application, such as U.S. Patent Application Serial Nos.: 10/306622 (Attorney Docket No. 021629-000110US), filed November 27, 2002; 10/306620 (Attorney Docket No. 021629-000210US), filed November 27, 2002; 10/306813 (Attorney Docket No. 021629-000320US), filed November 27, 2002; 10/412714 (Attorney Docket No. 021629-000330US), filed April 10, 2003; 10/637713 (Attorney Docket No. 021629-000340US), filed August 8, 2003; 10/624451 (Attorney Docket No. 021629-000400US), filed July 21, 2003; 10/738666 (Attorney Docket No. 021629-000510US), filed December 16, 2003; 10/458062 (Attorney Docket No. 021629-001800US), filed June 9, 2003; 10/686507 (Attorney Docket No. 021629-001900US), filed October 14, 2003; 10/686025 (Attorney Docket No. 021629-002000US), filed October 14, 2003; 10/687532 (Attorney Docket No. 021629-002100US), filed October 15, 2003; 10/46466 (Attorney Docket No. 021629-002200US), filed December 23, 2003; and 10/_____ (Attorney Docket No. 021629-002400US), filed March 3, 2004, all of which are hereby incorporated fully by reference. Although many improvements in stent design and stent delivery techniques have been suggested, improvements are still being sought.

[0009] For example, repair of vessels at areas of bifurcation is particularly challenging. A bifurcation of a vessel is generally a division into two branches, such as a main branch and a side branch. Generally, treatment of such bifurcated vessels with stents is difficult because it is technically challenging to place one or more stents in a main vessel and one or more stents in a branching vessel so as to sufficiently treat the existing lesion(s) while not interrupting blood flow through either the main or branch vessel. Oftentimes, if the main vessel is treated sufficiently with a stent, the stent disrupts flow into the branching vessel and/or makes placement of additional stents in the branching vessel quite difficult. In other cases, placement of a stent in the branching vessel may hinder stent placement and/or blood flow in the main vessel. Difficulties in stent-based treatment of bifurcated vessels occur due to limitations of both current stent designs and currently available stent delivery devices and techniques.

[0010] Some currently available systems for placing stents at an area of vessel bifurcation require placement of a first stent in one branch of the vessel, removal of the catheter from the

body, insertion of a second catheter to place a second stent, and so on until a desired number of stents is placed. Other available techniques involve insertion of two catheters simultaneously to place stents in two branches of a bifurcated vessel. A number of other alternative techniques and devices have been developed for treating vessel lesions at bifurcations. Some methods are described, for example, in U.S. Patent Nos. 6,033,434 and 6,582,394, as well as PCT Patent Application Publication No. WO 2004/017865.

[0011] All of these currently available devices and methods for delivering stents at vessel bifurcations have one or more drawbacks. Perhaps most obvious is the inconvenience and additional time and expense of using multiple catheters to place multiple stents in the bifurcated vessel. As discussed above, currently available devices and methods also do not provide for placement of custom length stents.

[0012] For these and other reasons, stents and stent delivery catheters are needed which facilitate treatment of vessels at areas of bifurcations. Ideally, such stents and delivery catheters would allow for placement of stents in a main vessel and a branch vessel, without requiring removal of the delivery catheter from the patient. Also ideally, customization of stent length *in situ* would be provided, as well as treatment of multiple lesions of various sizes, both without requiring removal of the delivery catheter from the patient. Such stents and stent delivery catheters should be capable of treating lesions of particularly long length and lesions in curved regions of a vessel, and should be highly flexible to conform to vessel shape and movement. Such stent delivery catheters should further be of minimal cross-sectional profile and should be highly flexible for endovascular positioning through tortuous vascular pathways. At least some of these objectives will be met by the present invention.

BRIEF SUMMARY OF THE INVENTION

[0013] The invention provides apparatus and methods for delivering prostheses or stents into bifurcated vessels. In one aspect of the invention, a method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, involves: positioning a delivery catheter in the main branch; deploying a first stent from the delivery catheter in the main branch; positioning the delivery catheter in the side branch; and deploying a second stent from the delivery catheter in the side branch. Using this method, the delivery catheter is not removed from the vessel between deploying the first and second stents.

[0014] In some embodiments, the method may optionally include deploying a third stent from the delivery catheter in the main branch or side branch without removing the delivery catheter from the vessel. In one embodiment, the delivery catheter is positioned through an opening in a sidewall of the first stent to deploy the second stent. In a preferred embodiment, the first and second stents each comprise a plurality of separable segments. Optionally, the first stent may have a different length than the second stent. In alternative embodiments, the first stent may be deployed before the second stent or the second stent may be deployed before the first stent. In some embodiments, the first stent and the second stent each have a portion in the main branch. Some embodiments of the method further include adjusting the length of the first and/or second stents before deploying the first and/or second stents while the delivery catheter remains in the vessel.

[0015] Optionally, some embodiments further include dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. Such dilating of a vessel before deploying a stent is often referred to as "pre-dilatation." In various embodiments, various different techniques for pre-dilatation and stent placement may be employed. For example, in one embodiment an expandable member may be used to pre-dilate a vessel, and then the same expandable member may be used to deploy and expandable stent. Sometimes, the same expandable member may additionally be used to further expand the stent after it has been deployed. In another embodiment, an expandable member may be used to pre-dilate a vessel and then self-expanding stent(s) may be deployed from the delivery catheter without using the expandable member for deployment. In another embodiment, a first expandable member may be used for pre-dilatation and a second expandable member on the same delivery catheter may be used to

deploy stent(s) in the vessel. Thus, any suitable combination of expandable members, pre-dilatation and stent delivery are contemplated within the scope of the invention. Stent delivery devices and methods involving pre-dilatation are described more fully in U.S. Patent Application Serial No. 10/_____ (Attorney Docket No. 021629-002400US), entitled "Stent Delivery Apparatus and Methods," filed March 3, 2004, which was previously incorporated by reference.

[0016] In another aspect of the invention, a method of treating one or more lesions in a vessel, the vessel having a first branch and a second branch meeting at a bifurcation, involves: positioning a delivery catheter in the first branch; deploying a first stent from the delivery catheter in the first branch, a portion of the first stent being disposed across the bifurcation; positioning the delivery catheter in the second branch through an opening in a sidewall of the first stent; and deploying a second stent from the delivery catheter, at least a portion of the second stent being disposed in the second branch. Again, using this method, the delivery catheter is not removed from the vessel between deploying the first and second stents.

[0017] In some embodiments, the method further includes dilating the opening in the sidewall of the first stent by expanding an expandable member on the delivery catheter. In one embodiment, before dilating, the opening in the sidewall of the first stent is I-shaped. Optionally, the first stent may have a first portion with a plurality of first slots and a second portion with a plurality of second slots, the first slots being larger than the second slots. In such embodiments, the opening in the sidewall of the first stent may comprise one of the first slots, and the first stent may be deployed so that at least one of the first slots is aligned with bifurcation.

[0018] In various embodiments, any of a number of suitable stents may be used. In one embodiment, for example, the first stent may have a different geometry than the second stent. In another embodiment, the first stent has a different length than the second stent. In some embodiments, at least one of the first and second stents comprises a plurality of separable segments.

[0019] As described above, in some embodiments deploying the first stent and/or the second stent comprises expanding an expandable member on the delivery catheter. In other embodiments, the stents may be self-expanding and may be deployed by releasing them from

the delivery catheter. Some embodiments may further include dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents.

[0020] In another aspect of the invention, a stent delivery device for treating one or more lesions in a vessel having a bifurcation, the bifurcation including a main branch and a side branch, includes: a catheter shaft; a first stent carried by the catheter shaft configured for deployment in the main branch; a second stent carried by the catheter shaft configured for deployment in the side branch; and a deployment mechanism for deploying the first and second stents independently of each other. In some embodiments, the deployment mechanism comprises an expandable member coupled to the catheter shaft, the first and second stents being positionable on the expandable member for expansion thereby. Such embodiments may optionally further include a sheath slidably disposed over the expandable member, the sheath being positionable to restrain a first portion of the expandable member while allowing expansion of a second portion of the expandable member. In some embodiments, the expandable member is configured for dilation of the vessel without deploying either of the first and second stents.

[0021] In some embodiments, either or both of the first and second stents may be self-expanding. Optionally, at least one of the first and second stents may have a sidewall opening that can be widened following stent deployment. In such embodiments, the other of the first and second stents may optionally be positionable through the sidewall opening. In one embodiment, the second stent has a different geometry, material, shape, and/or size than the first stent. Some embodiments further include a third stent carried by the catheter shaft and deployable independently of the first and second stents. In some embodiments, a length of at least one of the first and second stents may be selected in situ. Also in some embodiments, at least one of the first and second stents may comprise a plurality of separable stent segments.

[0022] Further aspects of the nature and advantages of the invention will become apparent from the detailed description below taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Fig. 1 is a perspective view of a stent delivery catheter with sheath retracted and expandable member inflated according to one embodiment of the invention.

[0024] Fig. 2A is a side cross-section of a distal portion of the stent delivery catheter of Fig. 1 with expandable member deflated and sheath advanced distally.

[0025] Fig. 2B is a side cross-section of a distal portion of the stent delivery catheter of Fig. 1 with expandable member inflated and sheath retracted.

[0026] Fig. 3A is a side view of a first embodiment of a stent segment in an unexpanded configuration according to one embodiment of the invention.

[0027] Fig. 3B is a side view of the stent segment of Fig. 3A in an expanded configuration.

[0028] Fig. 4A is a side view of a stent segment in an unexpanded configuration according to one embodiment of the invention.

[0029] Fig. 4B is a side view of two of the stent segments of Fig. 4A in an expanded configuration.

[0030] Fig. 5A is a perspective schematic view of a stent having a central portion and adjacent end portions according to one embodiment of the invention.

[0031] Figs. 5B-5D are schematic side views of various stents, each having a central portion and adjacent end portions, according to various embodiments of the invention.

[0032] Figs. 6A-6H are side cutaway views illustrating a method for treating lesions in a bifurcated vessel using a stent delivery catheter according to one embodiment of the invention.

[0033] Figs. 7A-7D are side cutaway views illustrating a method for treating lesions in a bifurcated vessel using a stent delivery catheter according to another embodiment of the invention.

[0034] Fig. 7E is a schematic side view of two overlapping stents placed according to a method as in Figs. 7A-7D.

[0035] Figs. 8A-8D are side cutaway views illustrating a method for treating lesions in a bifurcated vessel using a stent delivery catheter according to another embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0036] Referring to Fig. 1, in a first embodiment of the invention, a stent delivery catheter 20 comprises an elongate flexible shaft 22 having a proximal end 24 and a distal end 26. Shaft 22 is comprised of a plurality of coaxial members including an inflation shaft 34, a pusher 36, and a sheath 38. A handle 28 is mounted to sheath 38 at proximal end 24. Near distal end 26, expandable member 30, shown in an expanded configuration, is mounted at its proximal end to inflation shaft 34. A guidewire tube 40 extends through a port 42 in sheath 38 and extends through the interior of expandable member 30 to distal end 26. Expandable member 30 is attached at its distal end to guidewire tube 40, and a nosecone 32 is mounted to guidewire tube 40 distally of expandable member 30. A guidewire 44 is slidably positionable through guidewire tube 40 and nosecone 32 to facilitate guidance of catheter 20 through the vasculature.

[0037] A plurality of stent segments 46 are slidably positioned over expandable member 30. Pusher 36 is axially slidable relative to inflation shaft 34 and engages stent segments 46 at its distal end 48. Pusher 36 may be pushed distally to advance stent segments 46 over expandable member 30, or pusher 36 may be held in a stationary position while expandable member 30 is drawn proximally relative to stent segments 46. Sheath 38 is axially movable relative to expandable member 30, pusher 36, and stent segments 46. Sheath 38 may be repositioned proximally or distally to selectively expose a desired length of the expandable member and stent segments thereon according to the length of the lesion to be treated. Sheath 38 and pusher 36 may be drawn proximally in tandem relative to expandable member 30 to separate stent segments 46 exposed distally of sheath 38 from stent segments 46 held within sheath 38. Various other aspects of the construction of delivery catheter 20 and stent segments 46 are described in copending U.S. Patent Application Serial No. 10/637713, which was previously incorporated by reference.

[0038] A stent valve 50 is mounted to the interior of sheath 38 and is preferably spaced proximally from the distal end 52 of sheath 38 a distance equal to the length of about ½-1 stent segment. Stent valve 50 comprises an annular ridge configured to frictionally engage stent segments 46 to facilitate control of the spacing between those segments to be deployed distally of sheath 38 and those to be retained within sheath 38. Stent valve 50 may also comprise any of the structures described in copending U.S. Patent Application Serial No. 10/412714, which was previously incorporated by reference.

[0039] Handle 28 includes an actuator knob 54 rotatably coupled thereto. A post 56 is mounted to handle 28 so as to be extendable distally out of the handle and retractable proximally into the handle. Sheath 39 is attached to post 56. Rotation of actuator knob 54 extends or retracts post 56, thereby moving sheath 38 relative to expandable member 30. A lever 58 is pivotably coupled to handle 28 and is movable between a first position in which rotation of actuator knob 54 moves only sheath 38, and a second position in which rotation of actuator knob 54 moves both sheath 38 and pusher 36 relative to expandable member 30, as described more fully below.

[0040] A plurality of indicia 60 are disposed on post 56. Indicia 60 comprise alphanumeric symbols or other appropriate indicators of the length of expandable member exposed distally of sheath 38 and/or the number or length of stent segments 46 exposed for deployment. As described more fully below, a pointer or other reference object may be used that points to the appropriate location among indicia 60 corresponding to the number or length of stent segments 46 that have been exposed; preferably such pointer is adapted to compensate for retraction of sheath 38 in tandem with pusher 36, during which additional stent segments are not exposed distally of sheath 38, as described more fully below.

[0041] A luer fitting 62 is mounted to a proximal end of handle 28 and is in fluid communication with an inflation lumen (not shown in Fig. 1) in inflation shaft 34. Luer fitting 62 is adapted for coupling to an inflation device to enable delivery of inflation fluid into expandable member 30, for example, an Indeflator™ inflation device available from Guidant Corp. of Santa Clara, California.

[0042] Referring to Figs. 2A-2B, delivery catheter 20 includes a device for providing a tactile indication of the number of stent segments 46 exposed from sheath 38 in addition to the visual indication provided by indicia 60. In this embodiment, the indication device consists of a detent 66 extending inwardly from the inner wall of sheath 38, and a series of slots 68 arranged axially at spaced-apart locations on pusher 36. Detent 66 and slots 68 may be located in a distal portion of delivery catheter 20 just proximal to expandable member 30, in a middle portion of the catheter proximal to guidewire port 42, or near the proximal end 24 distally of or within post 56 or handle 28. Detent 66 is preferably a cantilevered extension integrally formed with sheath 38, being cut, for example, out of the wall of sheath 38, and is resiliently deflectable and biased toward pusher 36. Detent 66 may alternatively be a bump or ridge on the inner wall of sheath 38 configured to engage slots 68. Slots 68 may be holes,

apertures, depressions, recesses, ridges, bumps or any other suitable structure for receiving or catching on detent 66. The spacing of slots 68 is selected to provide an indication of the distance that sheath 38 is translated relative to pusher 36. In a preferred embodiment, the spacing is equal to the length of 1 stent segment 46, although ½, twice, or other known fraction or multiple of the length of a stent segment 46 are also possible. As sheath 38 is retracted proximally relative to pusher 36, detent 66 catches in each slot, providing a tactile "bump" that can be felt through handle 28. In this way, as knob 54 is turned to retract sheath 38, the user knows that each bump corresponds to the length of one stent segment, meaning that one stent segment has been exposed distally of sheath 38 with each bump. By feeling such bumps and by observing indicia 60, the user can precisely retract the sheath to expose the number of stent segments needed to match the length of the lesion being treated, as illustrated in Fig. 2B.

[0043] Further description of stent delivery catheter devices such as those illustrated by Figs. 1, 2A and 2B may be found in U.S. Patent Application No. 10/46466, which was previously incorporated by reference. Further detailed description of the distal portion of a stent delivery catheter may be found in U.S. Patent Application Serial No. 10/_____ (Attorney Docket No. 021629-002400US), which was previously incorporated by reference.

[0044] A first preferred geometry of stent segments 32 is illustrated in Figs. 3A-3B. Fig. 3A illustrates a portion of a stent segment 32 in an unexpanded configuration, shown in a planar shape for clarity. Stent segment 32 comprises two parallel rows 96A, 96B of I-shaped cells 100 formed around an axis A so that stent segment 32 has a cylindrical shape. Each cell 100 has upper and lower axial slots 102 aligned with the axial direction and a circumferential slot 104. Upper and lower slots 102 preferably have an oval, racetrack, rectangular or other oblong shape with a long dimension L generally parallel to axis A and a short dimension W perpendicular thereto. Axial slots 102 are bounded by upper axial struts 106 and lower axial struts 107, curved outer ends 108 and curved inner ends 110. Each circumferential slot 104 is bounded by an outer circumferential strut 109 and an inner circumferential strut 111. Each I-shaped cell 100 is connected to the adjacent I-shaped cell 100 in the same row 96A or 96B by a circumferential connecting strut 113. All or a portion of cells 100 in row 96A merge or join with cells 100 in row 96B at the inner ends 110, which are integrally formed with the inner ends 110 of the adjacent cells 100.

[0045] In a preferred embodiment, a spacing member 112 extends outwardly in the axial direction from a selected number of outer circumferential struts 109 and/or connecting struts 113. Spacing member 112 preferably itself forms a subcell 114 in its interior, but alternatively may be solid without any cell or opening therein. For those spacing members 112 attached to outer circumferential struts 109, subcell 114 preferably communicates with I-shaped cell 100. Spacing members 112 are configured to engage the curved outer ends 108 of an adjacent stent segment 32 so as to maintain appropriate spacing between adjacent stent segments. In one embodiment, spacing members 112 have outer ends 116 with two spaced-apart protrusions 118 that provide a cradle-like structure to index and stabilize the curved outer end 108 of the adjacent stent segment. Preferably, spacing members 112 have an axial length of at least about 10%, more preferably at least about 25%, of the long dimension L of I-shaped cells 100, so that the I-shaped cells 100 of adjacent stent segments are spaced apart at least that distance. Because spacing members 112 experience little or no axial shortening during expansion of stent segments 32, this minimum spacing between stent segments is maintained both in the unexpanded and expanded configurations.

[0046] Fig. 3B shows stent segment 32 of Fig. 3A in an expanded configuration. It may be seen that cells 100 are expanded so that upper and lower slots 102 are diamond shaped with circumferential slots 104 remaining basically unchanged. This results in some axial shortening of the stent segment, thereby increasing the spacing between adjacent stent segments. The stent geometry is optimized by balancing the amount of axial shortening and associated inter-segment spacing, the desired degree of vessel wall coverage, the desired metal density, and other factors. Because the stent is comprised of multiple unconnected stent segments 32, any desired number from 2 up to 10 or more stent segments may be deployed simultaneously to treat lesions of any length. Further, because such segments are unconnected to each other, the deployed stent structure is highly flexible and capable of deployment in long lesions having curves and other complex shapes.

[0047] As an additional feature, circumferential slots 104 provide a pathway through which vessel side branches can be accessed for catheter interventions. Should stent segment 32 be deployed at a location in which it covers the ostium of a side branch to which access is desired, a balloon dilatation catheter may be positioned through circumferential slot 104 and expanded. This deforms circumferential struts 109, 111 axially outward, thereby expanding circumferential slot 104 and further expanding upper and lower slots 102, as shown in

phantom in Fig. 3B. This provides a relatively large opening 120 through which a catheter may be inserted through stent segment 32 and into the side branch for placing stents, performing angioplasty, or carrying out other interventions. In preferred embodiments, opening 120 may be expanded to a diameter approximately as large as the expanded diameter of stent segments 32 to allow deployment of additional stent segments through opening 120.

[0048] Figs. 4A-4B illustrate a second preferred embodiment of a stent segment 32 according to the invention. In Fig. 4A, a portion of stent segment 32 is shown in a planar shape for clarity. Similar to the embodiment of Fig. 3A, stent segment 32 comprises two parallel rows 122A, 122B of I-shaped cells 124 formed into a cylindrical shape around axial axis A. Cells 124 have upper and lower axial slots 126 and a connecting circumferential slot 128. Upper and lower slots 126 are bounded by upper axial struts 130, lower axial struts 132, curved outer ends 134, and curved inner ends 136. Circumferential slots 128 are bounded by outer circumferential strut 138 and inner circumferential strut 140. Each I-shaped cell 124 is connected to the adjacent I-shaped cell 124 in the same row 122 by a circumferential connecting strut 142. Row 122A is connected to row 122B by the merger or joining of curved inner ends 136 of at least one of upper and lower slots 126 in each cell 124.

[0049] One of the differences between the embodiment of Figs. 4A-4B and that of Figs. 3A-3B is the way in which spacing is maintained between adjacent stent segments. In place of the spacing members 112 of the earlier embodiment, the embodiment of Fig. 4A includes a bulge 144 in upper and lower axial struts 130, 132 extending circumferentially outwardly from axial slots 126. These give axial slots 126 an arrowhead or cross shape at their inner and outer ends. The bulge 144 in each upper axial strut 130 extends toward the bulge 144 in a lower axial strut 132 in the same cell 100 or in an adjacent cell 100, thus creating a concave abutment 146 in the space between each axial slot 126. Concave abutments 146 are configured to receive and engage curved outer ends 134 of cells 124 in the adjacent stent segment, thereby maintaining spacing between the stent segments. The axial location of bulges 144 along upper and lower axial struts 130, 132 may be selected to provide the desired degree of inter-segment spacing.

[0050] Fig. 4B shows two stent segments 32 of Fig. 4A in an expanded condition. It may be seen that axial slots 124 are deformed into a circumferentially widened modified diamond shape with bulges 144 on the now diagonal upper and lower axial struts 130, 132. Circumferential slots 128 are generally the same size and shape as in the unexpanded

configuration. Bulges 144 have been pulled away from each other to some extent, but still provide a concave abutment 146 to maintain a minimum degree of spacing between adjacent stent segments. As in the earlier embodiment, some axial shortening of each segment occurs upon expansion and stent geometry can be optimized to provide the ideal intersegment spacing.

[0051] It should also be noted that the embodiment of Figs. 4A-4B retains the feature described above with respect to Figs. 3A-3B to enable access to vessel side branches blocked by stent segment 32. Should such side branch access be desired, a dilatation catheter may be inserted into circumferential slot 128 and expanded to provide an enlarged opening through which a side branch may be entered.

[0052] Referring now to Figs. 5A-5D, various embodiments of stents 30 may include a side access portion 152 and adjacent end portions 150. In some embodiments, side access portions 152 are configured with larger openings than end portions 150 to allow passage of a guidewire, stent delivery catheter and/or stent through the sidewall of side access portion 152. In other embodiments, side access portion 152 has struts which are made of a more flexible or deformable material to facilitate passage of a second stent therethrough. Thus, stent 30 may be placed in a main branch vessel with side access portion 152 positioned at an ostium of a side branch vessel bifurcating off of the main branch. A stent delivery catheter may then be passed through an opening in side access portion 152, into the side branch vessel, to place a second stent in the side branch. In some embodiments, the side branch stent may extend though side access portion 152 into the main branch. Methods for deploying such stents are described in further detail below.

[0053] In other embodiments, end portions 150 have a higher density of struts or material per unit length than side access portion 152. In other words, end portions 150 may be constructed of more dense material, may have a more dense pattern of struts, or both, relative to side access portion 152 in some embodiments. As shown in Fig. 5B, in one embodiment end portions 150 may have straight or I-shaped slots, and side access portion 152 may have a woven or cross-hatched geometry of diagonal struts. In another embodiment, as in Fig. 5C, side access portion 152 has linear struts aligned along the longitudinal axis of stent 30. In yet another embodiment, as in Fig. 5D, side access portion 152 has an undulating pattern. Various other embodiments of stents may have any other suitable configurations including a side access portion 152 with openings like those described above in reference to Figs. 3A and

3B or 4A and 4B, but which are larger than adjacent end portions 150. In various embodiments, stents 30 may be deployed by a number of different techniques. For example, in some embodiments, end portions 150 are balloon expandable while side access portion 152 is self-expanding, for example a side access portion 152 comprising shape memory or superelastic material. In other embodiments, all of stent 30 (both end portions 150 and side access portion 152) may be either self-expanding or balloon expandable. In some embodiments, an expandable member may be advanced through an opening in side access portion 152 and expanded to increase the size of the opening. Some embodiments may further include coupling means such as hooks, tabs or annular rib or rim on either or both of the main branch stent and side branch stent for coupling a side branch stent with side access portion 152. Side access portion 152 may be disposed centrally along the stent or may be offset toward the distal or proximal ends of the stent, and may even be at either end of the stent, as appropriate for the lesion to be treated. Multiple side access portions may also be included in the same stent.

[0054] Referring now to Figs. 6A-6H, one embodiment of a method for treating lesions in a bifurcated using a stent delivery catheter of the invention will be described. While the invention will be described in the context of coronary artery treatment, the invention is useful in any of a variety of bifurcated blood vessels and other body lumens in which stents are deployed, including the carotid, femoral, iliac and other arteries, as well as veins and other fluid-carrying vessels. A guiding catheter (not shown) is first inserted into a peripheral artery such as the femoral and advanced to the ostium of the target coronary artery A. Referring to Fig. 6A, a guidewire 168 is then inserted through the guiding catheter into the coronary artery A where one or more lesions L are to be treated. The proximal end of guidewire 168 is then inserted through a nosecone 164 of a stent delivery catheter 160 outside the patient's body, and stent delivery catheter 160 is slidably advanced over guidewire 168 and through the guiding catheter into the coronary artery A. During advancement, a sheath 162 is extended to nosecone 164 to surround the expandable member.

[0055] As shown in Fig. 6B, stent delivery catheter 160 is positioned through a lesion L to be treated such that nosecone 164 is distal to the lesion L. In one embodiment, catheter 160 is positioned first to treat a lesion in a main branch vessel MB of the coronary artery A. In alternative embodiments, catheter 160 may first be used to treat a lesion in a side branch vessel SB of the artery A.

[0056] Optionally, as shown in Fig. 6B, sheath 162 may be retracted and expandable member 166 expanded to predilate lesion L prior to stent deployment. Stent delivery catheter 160 may be used for predilitation by retracting sheath 162 along with stent segments (not shown) to expose an extremity of expandable member 166 long enough to extend through the entire lesion. (Alternatively, predilatation may be performed prior to introduction of stent delivery catheter 160 by inserting a separate angioplasty catheter over guidewire 168 and dilating lesion L.) This may be done while delivery catheter 160 is positioned proximally of lesion L or with expandable member 166 extending through lesion L. In some embodiments, fluoroscopy enables the user to visualize the extent of sheath retraction relative to lesion L by observing the position of a marker on sheath 162 relative to a marker at the distal end of expandable member 166. To allow stent segments to move proximally relative to expandable member 166, force is released from pusher tube 36 and valve member 50 (Figs. 2A and 2B) engages and draws the stent segments proximally with sheath 162. With the appropriate length of expandable member 166 exposed, inflation fluid is introduced through inflation lumen 34 to inflate expandable member 166 distally of sheath 162 and thereby dilate lesion L. Expandable member 166 is then deflated and retracted within sheath 162 while maintaining force on the pusher tube so that stent segments are positioned up to the distal end of expandable member 166, surrounded by sheath 162. Alternative embodiments of devices and methods for lesion predilatation are described in detail in U.S. Patent Application No. 10/_____ (Attorney Docket No. 021629-002400US), which was previously incorporated by reference.

[0057] Referring now to Fig. 6C, following any predilatation, stent delivery catheter 160 is repositioned in the main branch so that nosecone 164 is distal to the lesion (main branch MB lesion not visible in Fig. 6C). Sheath 162 is then retracted to expose a stent 170 having an appropriate number of stent segments 172 to cover the lesion. As sheath 162 is drawn proximally, force is maintained against pusher tube 36 so that stent segments 172 remain positioned up to the distal end of expandable member 166. Expandable member 166 is then inflated by delivering inflation fluid through inflation lumen 34, and the exposed distal portion of expandable member 166 expands so as to expand stent segments 172 thereon into engagement with the lesion. If predilatation was not performed, lesion L may be dilated during the deployment of stent segments 172 by appropriate expansion of expandable member 166. Sheath 162 constrains the expansion of the proximal portion of expandable member 166 and stent segments within sheath 162.

[0058] Expandable member 166 is then deflated, leaving stent segments 172 in a plastically-deformed, expanded configuration within lesion L, as shown in Fig. 6D. With stent segments 172 deployed, expandable member 166 may be retracted within sheath 162, again maintaining force against pusher tube 36 to position a second set of stent segments (not shown) at the distal end of expandable member 166. Expandable member 166 is moved proximally relative to the second stent segments until the distal-most stent segment engages stop 78 (Figs. 2A-2B), thereby placing second stent segments in position for deployment. Stent delivery catheter 160 is then ready to be repositioned at a different lesion L in the side branch vessel SB, as shown in Fig. 6D, or in the main branch MB in other embodiments. Guidewire 168 is first advanced into side branch SB, and catheter 160 is advanced over guidewire 168. Sheath 162 is again retracted and expandable member 166 expanded to dilate lesion L. Advantageously, multiple lesions of various lengths may be treated in this way without removing stent delivery catheter 160 from the patient's body.

[0059] Referring now to Fig. 6E, once positioned in the side branch SB, stent delivery catheter 160 may be used to deploy a second stent 180 at the lesion L in the side branch SB. The method for stent deployment may be carried out as described above. Delivery catheter 160 may then be removed from the side branch SB, realigned in the main branch, and expandable member 166 again inflated to dilate a third lesion L, as shown in Fig. 6F. As shown in Fig. 6G, stent delivery catheter 160 may next be used to deploy a third stent 190 having one or more stent segments 190 at another lesion L in the main branch MB. Fig. 6H shows three stents 170, 180, 190 in place in the main branch MB and side branch SB of the artery A, after stent delivery catheter 160 has been removed. In various alternative techniques, only one stent may be placed in each of the main and side branches, the side branch stent may be placed before the main branch stent, multiple stents may be placed in the side branch vessel, and or the like. Any suitable combination of stent placements is contemplated according to various embodiments of the invention. Furthermore, when movement of the pusher tube, sheath, or stent segments is described in relation to other components of the delivery catheter of the invention, such movement is relative and will encompass: moving the sheath, pusher tube, or stent segments while keeping the other component(s) stationary; keeping the sheath, pusher tube or stent segments stationary while moving the other component(s); or moving multiple components simultaneously relative to each other.

[0060] Referring now to Figs. 7A-7D, an alternative method for treating a bifurcated vessel is illustrated. As shown in Fig. 7A, a first stent 210 preferably having multiple stent segments 212 may be placed in the manner described above in a main branch MB of a vessel such that a central portion of first stent 210 crosses an ostium of (opening into) a side branch SB of the vessel. A guidewire 208 may then be extended through an opening in the sidewall of the central portion of first stent 210 into side branch SB and up to or past a side branch lesion L.

[0061] As shown in Fig. 7B, a stent delivery catheter 200 may then be advanced over guidewire 208, into side branch SB to a position for treating the lesion L. In some embodiments, a sheath 202 will first be retracted proximally from nosecone 204 to expose and allow expansion of an expandable member 206 to predilate the lesion L. In some embodiments, a portion of expanded expandable member 206 will extend through a sidewall opening 214 in first stent 210, and may be used to expand sidewall opening 214 either before or at the same time as it predilates the lesion L, deforming the struts around sidewall opening 214 to create a larger opening of a size sufficient to receive a second stent therethrough.

[0062] Referring now to Fig. 7C, a second stent 220 may then be placed in side branch SB using stent delivery catheter 200 (removed from Fig. 7C for clarity). In some embodiments, as in Figs. 7C and 7D, second stent 220 may extend through side-wall opening 214 of first stent 210, to extend back into the main branch MB, thus having a bend or "elbow" to conform to the longitudinal axis of the main branch. In alternative embodiments, the second stent may extend up to but not through sidewall opening 214, may extend up to and attach to sidewall opening 214, may be spaced apart from sidewall opening 214, or the like.

[0063] As shown in Figs. 7D and 7E, in one embodiment in which second stent 220 extends into the main branch MB, stent delivery catheter 200 may by advanced into main branch MB again, after placement of second stent 220, and expandable member 206 may be expanded so as to expand an opening 221 in the "elbow portion" of second stent 220 in alignment with the passage through first stent 210. Fig. 7E schematically shows first stent 210 overlapping second stent 214, the latter of which includes opening 221 in the "elbow portion" of the stent 214. . Such expansion of an opening of second stent 220 helps to prevent disruption of blood flow through the main branch MB due to the presence of second stent 220 within the main branch MB.

[0064] With reference now to Figs. 8A-8D, another embodiment of a method for treating bifurcated vessels is described. As shown in Fig. 8A, a first stent 240 is delivered via a stent deliver catheter (shown in Fig. 8B) in a main branch MB of the vessel, such that a central portion 244 of first stent 240 is positioned at an ostium of a side branch SB. First stent 240 is generally configured as the stents described above with reference to Figs. 5A-5D, thus having central portion 244 with one or more large sidewall openings and adjacent end portions 242 having smaller (or "higher density") sidewall openings. In one embodiment, central portion 244 is self-expanding while end portions 242 are balloon expandable. Central portion 244 may be positioned relative to the side branch SB ostium using fluoroscopy or any other suitable technique. A guidewire 238 may then be extended through a sidewall opening in central portion 244, into the side branch SB and up to or past a side branch lesion L.

[0065] As illustrated in Fig. 8B, a stent delivery catheter 230 may then be passed through the sidewall opening, over guidewire 238, and into the side branch SB. A sheath 232 may be retracted from the nosecone 234 to expose and allow expansion of an expandable member 236, to both predilate the lesion L and to expand the sidewall opening in central portion 244 by deforming or deflecting one or more struts 244a of central portion 244 adjacent the sidewall opening. As shown in Fig. 8C, delivery catheter 230 may then be used to deploy a second stent 250, as described above. Second stent 250 may also include a central portion 254 having large sidewall openings and adjacent end portions 252 having smaller sidewall openings. Again, as shown in Fig. 8D, delivery catheter 230 may be repositioned in the main branch MB after delivery of first stent 240 to expand a sidewall opening in second stent 250 to enhance blood flow through the main branch MB. The expanded opening in second stent 250 may in some embodiments lie in the central portion 254 of second stent 250.

[0066] While the foregoing description of the invention is directed to a stent delivery catheter for deploying stents into vascular lumens to maintain patency, various other types of wire-guided catheters also may embody the principles of the invention. For example, catheters for deployment of prosthetic devices such as embolic coils, stent grafts, aneurism repair devices, annuloplasty rings, heart valves, anastomosis devices, staples or clips, as well as ultrasound and angiography catheters, electrophysiological mapping and ablation catheters, and other devices may also utilize the principles of the invention.

[0067] Although the above is complete description of the preferred embodiments of the invention, various alternatives, additions, modifications and improvements may be made without departing from the scope thereof, which is defined by the claims.